SMITH KATZENSTEIN JENKINS LLP

April 24, 2025

***Via CM/ECF and Hand Delivery***

The Honorable Jennifer L. Hall
J. Caleb Boggs Federal Building
Unit 17, Room 6312
844 North King Street
Wilmington, DE 19801-3555

**Re:** ***Ingenus Pharmaceuticals, LLC* v. *Hetero USA, Inc. et al.***
**C.A. No. 24-1025-JLH**

Dear Judge Hall:

Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") requests that the Court order Defendants Hetero Labs Limited and Hetero Drugs Limited (collectively "Hetero") to comply with its discovery obligations by: (1) producing documents in response to Ingenus' Requests for Production ("RFPs") Nos. 2, 5-14, 16-18, and 20-36 (*see* Exhibit 1); and (2) responding to Ingenus' Interrogatory Nos. 1-3, 5-8, and 11 (Exh. 2).

On September 11, 2024, Ingenus sued Hetero for infringement of U.S. Patent No. 10,993,952 ("the '952 Patent) based on Hetero's submission of Abbreviated New Drug Application ("ANDA") No. 219271 to the U.S. Food and Drug Administration ("FDA), whereby Hetero seeks FDA approval to market and sell Cyclophosphamide Solution; 500mg/2.5ml (200mg/ml), lgm/5ml (200mg/ml), and 2gm/10ml (200mg/ml) ("Defendants' ANDA Products"). D.I. 1, 1. Ingenus served its first set of Interrogatories (Nos. 1-11) and RFPs (Nos. 1-41) on February 3, 2025. The discovery requests concern, *inter alia,* the development, manufacture, research, and composition of Hetero's ANDA Product, Hetero's awareness of and actions taken with respect to the'952 Patent, and Hetero's Paragraph IV Certification.

On March 5, 2025, Hetero objected to each of Ingenus' discovery requests, failed to substantively respond to any of Ingenus' interrogatories, and produced only its ANDA in response to Plaintiffs RFPs. Ingenus wrote to Hetero on March 16, 2025 to address Hetero's failure to comply with its discovery obligations. At a March 20, 2025 meet and confer, Hetero stated that its ANDA was the only relevant responsive document in its possession. Hetero agreed to supplement its response to Ingenus' Interrogatory No. 9, which sought the factual and legal bases for Hetero's claims of invalidity and noninfringement, and to conduct a search[1] for (but not produce) documents concerning sales, marketing, advertising, and testing for its ANDA Product. Exh. 3. While Hetero later indicated that it did "not have any documents related to projected sales, marketing, or advertising" (Exh. 4.), Hetero failed to produce documents concerning the following, all of which are routinely produced in ANDA litigations:

- Studies/evaluations and tests associated with Hetero's ANDA or cyclophosphamide (RFP Nos. 2, 8, 14, 18) or '952 patent (and those related thereto) (RFP No. 36);
- Hetero's Paragraph IV Certification (RFP No. 5);
- Hetero's proposed label and package inserts (RFP Nos. 6-7);
- Manufacture and importation of Hetero's ANDA Product, and products containing cyclophosphamide (RFP Nos. 9-10, 13, 16-18, 35);
- Research, development, and formulation of Hetero's ANDA Product or any of its cyclophosphamide-containing compositions (RFP Nos. 14, 21, 23-24, 26, 28, 33);
- Stability, purity, and degradation of Hetero's ANDA Product (RFP No. 25, 27, 34);
- Efforts to combine cyclophosphamide with solvents and/or antioxidants (RFP Nos. 29-31);
- Comparisons of Hetero's ANDA Product and any other cyclophosphamide-containing composition (RFP No. 32);

[1] Prior to the meet and confer, Hetero objected to Ingenus' RFPs concerning these topics, but had no idea whether any responsive documents existed. *See* Exh. 3.

- Hetero's organizational structure and the names of its employees (RFP No. 20)[2];

Indeed, Hetero has not produced a single email or correspondence. After producing its ANDA in March, Hetero supplemented its production with its invalidity contentions on April 21st to include four (alleged) prior art documents and a spreadsheet from 2015 containing formulation ingredients. . Hetero has still not stated whether any documents were being withheld based on its objections, in violation of Fed. R. Civ. P. 34(b)(2)(C).

Hetero asserts that these requested documents are not relevant, and goes as far as to claim *without authority* that the only relevant document it must produce is its ANDA. Hetero cites to *Bayer AG v. Elan Pharm. Research Corp*., 212 F.3d 1241, 1248 (Fed. Cir. 2000) in its objections. *See e.g.*, Exhs. 1, at 32; 2, at 5. *Bayer* is not a discovery case and does not stand for the proposition that a Hatch-Waxman defendant need only produce its ANDA. Rather, in *Bayer*, the Federal Circuit affirmed summary judgment of noninfringement based on the defendant's ANDA, but was clear in explaining that "it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, ***and any other relevant evidence.***" *Id*., at 1249 (emphasis added); *see also Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562, 1568 (Fed. Cir. 1997) (same). Hetero's position on only producing its ANDA is particularly egregious where, as here, the ANDA is ***not dispositive of the infringement question*** since it does not address the testing conditions recited in Claim 1 for measuring impurities A, B and D. *Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379, 1384 (Fed. Cir. 2022)("If the ANDA specification does not speak clearly and directly to [] infringement, courts may look to other relevant evidence. . . .").

The relevancy standard in this Circuit is undemanding and liberal. *Crozer Chester Med. Ctr. v. NLRB*, 2023 U.S. App. LEXIS 9393, at *6 (3d Cir. Apr. 20, 2023). Courts in this district and elsewhere routinely compel the production of documents beyond a defendant's ANDA as being relevant to infringement and validity. *Vertex Pharm. Inc. v. Sun Pharm. Ind. Ltd*., No. 1-20-cv-00988 (D. Del. Apr. 24, 2023) ("Federal Circuit caselaw states that evidence beyond the ANDA can be relevant. . . At the discovery stage, then, the Court cannot definitively conclude that inquiries [beyond the ANDA] should be off limits as to literal infringement issues."). *Abraxis BioScience v. Actavis LLC*, 2017 U.S. Dist. LEXIS 229498, at *5-6 (D.N.J. Sep. 12, 2017) (Ordering production of documents relating to the actual and attempted development of the ANDA product, in addition to the ANDA) ("The Court is satisfied that product development documents are likely relevant to multiple secondary considerations of non-obviousness."); *Otsuka Pharm. Co. v. Apotex Corp*., 2008 U.S. Dist. LEXIS 73515, at *14-15 (D.N.J. Sep. 12, 2008) (Ordering the production of information beyond defendant's ANDA, concerning "the basis for Apotex filing an ANDA [] and the factual bases underlying Apotex's paragraph IV notice letter."); *Roxane Labs., Inc. v. Abbott Labs*., 2013 U.S. Dist. LEXIS 61556, at *13-14 (S.D. Ohio Apr. 30, 2013) (Ordering production of documents relating to the "investigation of and/or decision not to pursue" alternative formulations); *Eli Lilly & Co. v. Wockhardt Ltd*., 2010 U.S. Dist. LEXIS 52406, at *8-9 (S.D. Ind. May 27, 2010) (gathering cases) (Ordering production of documents "concerning Wockhardt's decision-making, proposed marketing, proposed market share, correspondence with FDA concerning proposed labeling, meeting minutes, emails, spreadsheets, PowerPoint presentations,

[2] As explained during the meet and confer, this request will help Plaintiff identify fact witnesses. *Sanghavi v. Navient Corp*., 2020 U.S. Dist. LEXIS 91290, at *5-6 (D.N.J. May 22, 2020).

reports, memoranda, and laboratory notebooks."); *Eli Lilly and Co. v. Teva Pharms. USA, Inc*., (S.D. Ind. July 29, 2008) (Ordering production of analyses, methods, bioequivalence studies, communications with FDA); *SmithKline Beecham Corp. v. Apotex Corp*., 1999 U.S. Dist. LEXIS 7249, 1999 WL 311697, at *8 (N.D. Ill. May 13, 1999) (Ordering production of laboratory notebooks).

Hetero's proportionality objection is without merit, since it was lodged before Hetero performed a search, or identified the number of documents that might fall within the scope of Plaintiff's requests, the time and expenses required to respond to those requests, or the potential disruption of plaintiff's business operations caused by its efforts to respond. *Astellas Pharma Inc. et al v. Lupin Ltd*., No. 1-23-cv-00819 (D. Del. Dec. 19, 2024) ("The Court is in no position to determine that, as Zydus suggests[,] the cost or burden to produce any such documents at issue or provide any such information would be disproportionate to the needs of the case (since the Court has not been given any relevant information that would substantiate such a claim)."); *Magnolia Med. Techs., Inc. v. Kurin, Inc*., 19−cv−00097−CFC−CJB19−cv−00097−CFC−CJB (D. Del. Sept. 1, 2020) (same). Hetero's privilege objection is addressed by a privilege log it may serve in accordance with the Scheduling Order. Finally, the Stipulated Protective Order (D.I. 25) addresses its confidentiality concerns relating to non-parties. D.I. 36, 2.

Hetero's failure to substantively respond to Ingenus' Interrogatories is equally inexcusable. In response to nearly all of Ingenus' Interrogatories, Hetero objects on relevance, directing Ingenus to its ANDA, arguing that "Hetero's ANDA defines the product described therein in a way that directly addresses the question of infringement in this case." Specifically, Hetero directed Ingenus to its ANDA for interrogatories calling for a description/identification of: circumstances surrounding considerations, preparations, and decision on the ANDA (No. 1); research, testing, studies, development, and manufacturing of the ANDA Product (No. 2); cyclophosphamide-containing formulations considered for the ANDA Product (No. 3); *whether* there was any evaluation/investigation conducted with respect to the '952 and related patent(s)/applications (No. 6); persons involved in the preparation of Hetero's Notice Letter and Paragraph IV Certification (No. 7); *identification* of efforts to determine whether Hetero's ANDA infringes the '952 Patent (No. 8); and *whether* Hetero has ever tested their proposed ANDA Product or Ingenus' commercial cyclophosphamide product for the presence of any impurities (No. 11).[3] Hetero's objection to Ingenus' Interrogatory No. 5 (seeking Hetero's first awareness of the '952 Patent) as irrelevant is poorly taken, given that "knowledge" of the patent is an element of proving indirect infringement.

Plaintiff requests the Court to overrule Hetero's objections, and order it to meaningfully respond to Ingenus' discovery requests. Plaintiff also requests that it be awarded its attorney's fees and reasonable expenses incurred in bringing this motion, as required under Fed. R. Civ. P. 37(a)(5)(A). *DeHart v. HomEq Servicing Corp.*, 679 F. App'x 184, 191 (3d Cir. 2017)("As required by [Fed. R. Civ. P. ] 37(a)(5), upon granting a motion to compel, the court must order payment of the movant's reasonable expenses incurred in making the motion, unless certain conditions apply, such as substantial justification for the failure to respond"); *Lightstyles, Ltd. v. Marvin Lumber & Cedar Co.*, 2015 U.S. Dist. LEXIS 87049 at *3 (M.D. Pa. July 6, 2015) (same).

[3] Hetero directed Ingneus to its ANDA in Rule 33(d) responses to Interrogatories Nos. 2-3 and 11.

Respectfully submitted,

*/s/ Neal C. Belgam*
Neal C. Belgam (No. 2721)